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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,763	09/17/2001	Paul J. Thompson	11576.51USI1	8878
23552	7590	11/24/2004	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			WEBB, SARAH K	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/954,763	Applicant(s) THOMPSON ET AL.	
	Examiner Sarah K Webb	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21, 23, 25, 26 and 28-34 is/are pending in the application.
4a) Of the above claim(s) 9, 12, 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 11, 13, 14, 17-21, 23, 25, 26, 28-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 9 is objected to because of the following informalities: The status identifier should be "withdrawn" instead of "original." Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 25,26,28,29,31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,129,700 to Fitz in view of US Patent No. 5,571,086 to Kaplan et al.

As clearly illustrated in Figure 5, the device includes an outer tubular member (22), inner tubular member (16), fluid channel (24) between the outer and inner tubular members, and stent (14) mounted on the distal end of the inner tubular member (16). It is inherent from the disclosure that a port in communication with the fluid channel (24) is included to provide fluid to the channel (24).

A discharge opening (54), or "fluid exchange aperture", at the distal end of the outer tubular member (22) allows fluid to flow from the fluid channel (24) to a patient's lumen (column 4, lines 25-35). There is a plurality of such apertures (54), and the apertures (54) are located on the portion of the outer tubular member (22) covering the

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stent. The stent is self-expanding (column 3, line 41) and is deployed by retracting the outer tubular member (22) (column 4, line 64), as shown in Figure 7. The inner tubular member (16) is hollow and defines a guide wire lumen (18).

Fitz includes all the limitations of claims 27 and 32 except for providing fluid exchange apertures at both the proximal and distal ends of the stent. Kaplan discloses an outer catheter that can be used with a stent delivery catheter (abstract, line 7).

Figure 13D best illustrates an array of **fluid exchange apertures (218)** positioned along a balloon region on the catheter (200). Kaplan teaches by illustration that the array of apertures (218) can extend over a length of a catheter (200) to encompass both the proximal and distal ends of a dilation balloon. The balloon (280) here would be analogous to the stent location area of Fitz. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include apertures in the outer tubular member at both the proximal and distal ends of the stent area of Fitz, as Kaplan teaches that this is another way to convey fluids to a patient's lumen from a catheter.

3. Claims 1-8,10,11,13,14,17-21,23,33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fitz in view of US Patent No. 5,279,546 to Mische et al.

As explained above, Fitz discloses a stent delivery catheter that includes most of the limitations of claim 1. Fitz fails to include a plurality of spacers in the fluid channel. Mische discloses a similar balloon catheter device. Mische includes an outer tubular member (70) and an inner tubular member (72) that define a fluid channel in between them. A plurality of spaced apart spacer members (134,136,138,140) are positioned in

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the lumen between the two tubular members (see Figure 3). Mische teaches that the spacers (134,136,138,140) provide resistance to luminal collapse (column 5, lines 35-36). The spacers also extend a majority of the longitudinal length of the catheter system, as this structure extends from the proximal hub (10) to the distal balloon section (74). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include spacers along the majority of the length of the lumen between the inner and outer tubular members of Fitz, as Mische teaches that this structure provides the catheter with resistance to luminal collapse.

The spacers are considered to meet the limitation of "splines." Further, the splines of Mische are coupled to the inner tubular member (72) and project outwardly toward the outer member (70).

Regarding claims 17 and 18, a surface capable of being thermally bonded falls within the scope of "a thermal bonding surface." Mische clearly includes a surface on the spacers that is capable of receiving a thermal bonding treatment to fixedly couple the inner and outer tubular members.

4. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fitz in view of Kaplan, as applied to claim 25 above, and in further view of US Patent No. 5,005,584 to Little.

Fitz includes all the limitations of claim 30, except for a pressure measuring device. Little discloses a guide wire that measures fluid pressure and is capable of being used with the Fitz device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the Little guide wire for the guide

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wire of Fitz, as this produces a combination that is capable of measuring fluid pressure within a passageway.

Response to Arguments

5. Applicant's arguments filed 9/13/04 have been fully considered but they are not persuasive. Applicant argues that Kaplan does not teach fluid exchange apertures at opposite ends of a stent region, and argues that perfusion ports 301 are located only at the proximal end of the stent. Examiner agrees that perfusion ports 301 are only located at the proximal end of the stent region, but examiner did not reference perfusion ports 301 in the prior office action. Examiner specifically pointed out the array of **apertures 218 in Figure 13D**, which clearly extend over the length of a region analogous to a stent region. Kaplan shows that it is within the level of ordinary skill in the art to provide fluid exchange apertures over a length at the distal end of a catheter.

6. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

7. Applicant argues that Mische does not teach or suggest a spacer located between inner and outer catheters. Claim 1 states, "*at least one spacer disposed within*

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said fluid channel between said inner tubular member and said outer tubular member."

The "spacer" of Mische is clearly disposed within the fluid channel between the two tubular members. Mische also teaches that the spacers (134,136,138,140) provide resistance to luminal collapse (column 5, lines 35-36). Mische teaches the required structure and provides motivation for including the "spacers" between two tubes.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhthuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
11/18/04

SKW

Julian W. Woo

**JULIAN W. WOO
PRIMARY EXAMINER**